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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,901	02/09/2001	Charlene A. Boehm	46607-248184	6758
7590		03/11/2005	EXAMINER	
Charlene A. Boehm		MARSCHEL, ARDIN H		
320 Gilbert Road		ART UNIT		
Columbus, NC 28722		PAPER NUMBER		

1631

DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/780,901

Applicant(s)

BOEHM, CHARLENE A.

Examiner

Ardin Marschel

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 4-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 4-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: 3/8/05.

- 5) ☐ Notice of Informal Patent Application (PTO-152)

- 6) ☒ Other: PATENT RULES pages R-79-R-82, R-84

### **DETAILED ACTION**

Due to newly applied rejections as noted below, the Finality of the Office action, mailed 9/9/04, is hereby withdrawn.

Applicants' arguments, filed 1/7/05, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### **IMPROPER AMENDING FORM**

The amendment to claim 5, filed 1/7/05, is improper due to utilizing an incorrect status identifier as "(Original)". The proper identifier should be "(Currently amended)". Also, a complete listing of the status of all claims ever presented including the text of all pending claims was not presented. Attached is a copy of pages R-79 through R-82 of the Manual of Patent Examination Procedure (MPEP) which summarizes the requirements for claim amending form and content.

### **LACK OF ENABLEMENT**

Claims 1, 2, and 4-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

This rejection is maintained and reiterated from the previous office action, mailed 9/9/04.

Applicant points to US. Patent No. 6,060,293 regarding chain molecule length for the computation of an electromagnetic resonant frequency. In response, each application for a Patent must be considered on its own merits.

It is also acknowledged that applicant's REMARKS, filed 1/7/05, contains what may be evidence of efficacy, predictability, and repeatability of the method under consideration. In order to properly consider such evidence it must be submitted in the form of a Declaration under 37 CFR 1.132. See the attached page R-84 of the MPEP regarding such a Declaration. Further consideration of the case results in Examples 1 -

8 reveals that the frequency protocol was stated as being "(as described in this application)" but without specifically indicating that the applied radiation frequency was as claimed which is a particular "second resonant frequency". Thus, the case studies are non-persuasive as not being directed specifically to the specificity as being claimed in said "second resonant frequency".

Applicant then argues that DNA is not conductive as metal antennas which were described in support of this rejection in the previous office action, mailed 9/9/04. The arguments indicate that DNA conductivity is an unsolved problem. In response, the conductivity of DNA is utilized in two Patent references which indicate DNA wire usage. See, for example Keen (US Patent No. 6,060,327) which states in column 7, lines 55-63, that double stranded DNA are conductive polymer strands. Batz et al. (US Patent No. 6,310,179) in column 7, lines 37-45, that double stranded nucleic acids are utilized therein as wires or conducting elements. Further in column 8, lines 30-44, the structures discussed therein are described as containing heterocyclic double stranded structures which are utilized as a conductor for electrons or a "transfer scaffold "wire".

Applicant goes on to argue that flexible coiled and supercoiled DNA maintains its average base pair measurement parameter. This sizing of a base pair does not negate the overall coiled or supercoiled nature of DNA which greatly affects the resonant frequency of a material such as an antenna to received electromagnetic energy. Applicant then argues that DNA crystalline characteristics do not require a straight form for responding to electromagnetic radiation. In response, the instant application is directed to determining a resonant frequency, not merely responding to radiation. The

straight vs. coiled nature of DNA has a great effect on this "resonant" frequency predictability as set forth in the previous office action and not negated by this generic responsive to electromagnetic radiation argument. Further arguments regarding responsiveness of DNA also lack the effects on the instantly claimed resonance and are thus non-persuasive.

### **VAGUENESS AND INDEFINITENESS**

Claims 1, 2, and 4-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, last 3 lines, the selective influencing of target genomic material is set forth via emitting into the medium surrounding the target genomic material. This seems to indicate that the electromagnetic radiation is emitted into material that is not the target genomic material which causes the claim to be vague and indefinite as to whether the practice is directed to influencing target genomic material or actually influencing the surrounding medium. Claims 15, 17, and 28 also contain this unclarity as also claims dependent from claims 1, 15, 17, and 28 via their dependence. Clarification via clearer claim wording is requested.

Also, these last 3 lines of claim 1 and correspondingly the other depending claims cite the emission of a "resonant frequency" wherein a frequency is a characteristic of electromagnetic radiation, for example. Does applicant intend that electromagnetic radiation or energy is emitted by the frequency-emitting device in the

Art Unit: 1631

claims or only a "characteristic" of such radiation or energy? Clarification via clearer claim wording is requested.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., AU 1631 Supervisory Patent Examiner, whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 8, 2005

 3/8/05  
**ARDIN H. MARSCHEL**  
**SUPERVISORY PATENT EXAMINER**

**§ 1.116 Amendments after final action or appeal.**

(a) An amendment after final action or appeal must comply with § 1.114 or this section.

(b) After a final rejection or other final action (§ 1.113) in an application or in an *ex parte* reexamination filed under § 1.510, or an action closing prosecution (§ 1.949) in an *inter partes* reexamination filed under § 1.913, amendments may be made canceling claims or complying with any requirement of form expressly set forth in a previous Office action. Amendments presenting rejected claims in better form for consideration on appeal may be admitted. The admission of, or refusal to admit, any amendment after a final rejection, a final action, an action closing prosecution, or any related proceedings will not operate to relieve the application or patent under reexamination from its condition as subject to appeal or to save the application from abandonment under § 1.135, or the reexamination from termination. No amendment can be made in an *inter partes* reexamination proceeding after the right of appeal notice under § 1.953 except as provided for in paragraph (d) of this section.

(c) If amendments touching the merits of the application or patent under reexamination are presented after final rejection, or after appeal has been taken, or when such amendment might not otherwise be proper, they may be admitted upon a showing of good and sufficient reasons why they are necessary and were not earlier presented.

(d) No amendment can be made as a matter of right in appealed cases. After decision on appeal, amendments can only be made as provided in §§ 1.198 and 1.981, or to carry into effect a recommendation under § 1.196 or § 1.977.

[24 FR 10332, Dec. 22, 1959; 46 FR 29183, May 29, 1981; para. (a) revised, 62 FR 53131, Oct. 10, 1997, effective Dec. 1, 1997; revised, 65 FR 14865, Mar. 20, 2000, effective May 29, 2000 (adopted as final, 65 FR 50092, Aug. 16, 2000); paras. (b) and (d) revised, 65 FR 76756, Dec. 7, 2000, effective Feb. 5, 2001]

**§ 1.117 [Reserved]**

[Removed and reserved, 62 FR 53131, Oct. 10, 1997, effective Dec. 1, 1997]

**§ 1.118 [Reserved]**

[48 FR 2712, Jan. 20, 1983, effective Feb. 27, 1983; removed and reserved, 62 FR 53131, Oct. 10, 1997, effective Dec. 1, 1997]

**§ 1.119 [Reserved]**

[32 FR 13583, Sept. 28, 1967; removed and reserved, 62 FR 53131, Oct. 10, 1997, effective Dec. 1, 1997]

**§ 1.121 Manner of making amendments in applications.**

(a) *Amendments in applications, other than reissue applications.* Amendments in applications, other than reissue applications, are made by filing a paper, in compliance with § 1.52, directing that specified amendments be made.

(b) *Specification.* Amendments to the specification, other than the claims, computer listings (§ 1.96) and sequence listings (§ 1.825), must be made by adding, deleting or replacing a paragraph, by replacing a section, or by a substitute specification, in the manner specified in this section.

(1) *Amendment to delete, replace, or add a paragraph.* Amendments to the specification, including amendment to a section heading or the title of the invention which are considered for amendment purposes to be an amendment of a paragraph, must be made by submitting:

(i) An instruction, which unambiguously identifies the location, to delete one or more paragraphs of the specification, replace a paragraph with one or more replacement paragraphs, or add one or more paragraphs;

(ii) The full text of any replacement paragraph with markings to show all the changes relative to the previous version of the paragraph. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strikethrough cannot be easily perceived;

(iii) The full text of any added paragraphs without any underlining; and;



(iv) The text of a paragraph to be deleted must not be presented with strike-through or placed within double brackets. The instruction to delete may identify a paragraph by its paragraph number or include a few words from the beginning, and end, of the paragraph, if needed for paragraph identification purposes.

(2) *Amendment by replacement section.* If the sections of the specification contain section headings as provided in § 1.77(b), § 1.154(b), or § 1.163(c), amendments to the specification, other than the claims, may be made by submitting:

(i) A reference to the section heading along with an instruction, which unambiguously identifies the location, to delete that section of the specification and to replace such deleted section with a replacement section; and;

(ii) A replacement section with markings to show all changes relative to the previous version of the section. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived.

(3) *Amendment by substitute specification.* The specification, other than the claims, may also be amended by submitting:

(i) An instruction to replace the specification; and

(ii) A substitute specification in compliance with §§ 1.125(b) and (c).

(4) *Reinstatement of previously deleted paragraph or section.* A previously deleted paragraph or section may be reinstated only by a subsequent amendment adding the previously deleted paragraph or section.

(5) *Presentation in subsequent amendment document.* Once a paragraph or section is amended in a first amendment document, the paragraph or section shall not be represented in a subsequent amendment document unless it is amended again or a substitute specification is provided.

(c) *Claims.* Amendments to a claim must be made by rewriting the entire claim with all changes (e.g., additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

(1) *Claim listing.* All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of "canceled" or "not entered" may be aggregated into one statement (e.g., Claims 1–5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.

(2) *When claim text with markings is required.* All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of "currently amended," and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of "currently amended," or "withdrawn" if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as "withdrawn— currently amended."

(3) *When claim text in clean version is required.* The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, *i.e.*, without any markings in the presentation of text. The presentation of a clean version of any claim having the status of "original," "withdrawn" or "previously presented" will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of "withdrawn" or "previously presented." Any claim added by amendment must be indicated with the status of "new" and presented in clean version, *i.e.*, without any underlining.

(4) *When claim text shall not be presented; canceling a claim.*

(i) No claim text shall be presented for any claim in the claim listing with the status of "canceled" or "not entered."

(ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as "canceled" will constitute an instruction to cancel the claim.

(5) *Reinstatement of previously canceled claim.* A claim which was previously canceled may be reinstated only by adding the claim as a "new" claim with a new claim number.

(d) *Drawings.* One or more application drawings shall be amended in the following manner: Any changes to an application drawing must be in compliance with § 1.84 and must be submitted on a replacement sheet of drawings which shall be an attachment to the amendment document and, in the header, labeled "Replacement Sheet." Any replacement sheet of drawings shall include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is amended. All changes to the drawing(s) shall be explained, in detail, in either the drawing amendment or remarks section of the amendment paper.

(1) A marked-up copy of any amended drawing figure, including annotations indicating the changes made, may be included. The marked-up copy

must be clearly labeled as "Annotated Marked-up Drawings" and must be presented in the amendment or remarks section that explains the change to the drawings.

(2) A marked-up copy of any amended drawing figure, including annotations indicating the changes made, must be provided when required by the examiner.

(e) *Disclosure consistency.* The disclosure must be amended, when required by the Office, to correct inaccuracies of description and definition, and to secure substantial correspondence between the claims, the remainder of the specification, and the drawings.

(f) *No new matter.* No amendment may introduce new matter into the disclosure of an application.

(g) *Exception for examiner's amendments.* Changes to the specification, including the claims, of an application made by the Office in an examiner's amendment may be made by specific instructions to insert or delete subject matter set forth in the examiner's amendment by identifying the precise point in the specification or the claim(s) where the insertion or deletion is to be made. Compliance with paragraphs (b)(1), (b)(2), or (c) of this section is not required.

(h) *Amendment sections.* Each section of an amendment document (*e.g.*, amendment to the claims, amendment to the specification, replacement drawings, and remarks) must begin on a separate sheet.

(i) *Amendments in reissue applications.* Any amendment to the description and claims in reissue applications must be made in accordance with § 1.173.

(j) *Amendments in reexamination proceedings.* Any proposed amendment to the description and claims in patents involved in reexamination proceedings must be made in accordance with § 1.530.

(k) *Amendments in provisional applications.* Amendments in provisional applications are not usually made. If an amendment is made to a provisional application, however, it must comply with the provisions of this section. Any amendments to a provisional application shall be placed in the provisional application file but may not be entered.

[32 FR 13583, Sept. 28, 1967; 46 FR 29183, May 29, 1981; para. (e), 49 FR 555, Jan. 4, 1984, effective Apr. 1, 1984; revised, 62 FR 53131, Oct. 10, 1997, effective Dec. 1, 1997; revised, 65 FR 54604, Sept. 8, 2000, effective Nov. 7, 2000; para. (i) revised, 65 FR 76756, Dec. 7, 2000, effective Feb. 5, 2001; revised, 68 FR 38611, June 30, 2003, effective July 30, 2003]

#### § 1.122 [Reserved]

[24 FR 10332, Dec. 22, 1959; para. (b), 49 FR 48416, Dec. 12, 1984, effective Feb. 11, 1985; removed and reserved, 62 FR 53131, Oct. 10, 1997, effective Dec. 1, 1997]

#### § 1.123 [Reserved]

[48 FR 2712, Jan. 20, 1983, effective Feb. 27, 1983; 49 FR 555, Jan. 4, 1984, effective Apr. 1, 1984; amended, 58 FR 38719, July 20, 1993, effective Oct. 1, 1993; removed and reserved, 62 FR 53131, Oct. 10, 1997, effective Dec. 1, 1997]

#### § 1.124 [Reserved]

[Removed and reserved, 62 FR 53131, Oct. 10, 1997, effective Dec. 1, 1997]

#### § 1.125 Substitute specification.

(a) If the number or nature of the amendments or the legibility of the application papers renders it difficult to consider the application, or to arrange the papers for printing or copying, the Office may require the entire specification, including the claims, or any part thereof, be rewritten.

(b) Subject to § 1.312, a substitute specification, excluding the claims, may be filed at any point up to payment of the issue fee if it is accompanied by a statement that the substitute specification includes no new matter.

(c) A substitute specification submitted under this section must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter

must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown pursuant to this paragraph.

(d) A substitute specification under this section is not permitted in a reissue application or in a reexamination proceeding.

[48 FR 2712, Jan. 20, 1983, effective Feb. 27, 1983; revised, 62 FR 53131, Oct. 10, 1997, effective Dec. 1, 1997; paras. (b)(2) and (c) revised, 65 FR 54604, Sept. 8, 2000, effective Nov. 7, 2000; paras. (b) and (c) revised, 68 FR 38611, June 30, 2003, effective July 30, 2003]

#### § 1.126 Numbering of claims.

The original numbering of the claims must be preserved throughout the prosecution. When claims are canceled the remaining claims must not be renumbered. When claims are added, they must be numbered by the applicant consecutively beginning with the number next following the highest numbered claim previously presented (whether entered or not). When the application is ready for allowance, the examiner, if necessary, will renumber the claims consecutively in the order in which they appear or in such order as may have been requested by applicant.

[32 FR 13583, Sept. 28, 1967; revised, 62 FR 53131, Oct. 10, 1997, effective Dec. 1, 1997]

#### § 1.127 Petition from refusal to admit amendment.

From the refusal of the primary examiner to admit an amendment, in whole or in part, a petition will lie to the Director under § 1.181.

[Revised, 68 FR 14332, Mar. 25, 2003, effective May 1, 2003]

### TRANSITIONAL PROVISIONS

#### § 1.129 Transitional procedures for limited examination after final rejection and restriction practice.

(a) An applicant in an application, other than for reissue or a design patent, that has been pending for at least two years as of June 8, 1995, taking into

102(b), and the inventions defined by the claims in the application or patent under reexamination and by the claims in the patent or published application are not identical but are not patentably distinct, and the inventions are owned by the same party, the applicant or owner of the patent under reexamination may disqualify the patent or patent application publication as prior art. The patent or patent application publication can be disqualified as prior art by submission of:

(1) A terminal disclaimer in accordance with § 1.321(c); and

(2) An oath or declaration stating that the application or patent under reexamination and patent or published application are currently owned by the same party, and that the inventor named in the application or patent under reexamination is the prior inventor under 35 U.S.C. 104.

(b) When an application or a patent under reexamination claims an invention which is not patentably distinct from an invention claimed in a commonly owned patent with the same or a different inventive entity, a double patenting rejection will be made in the application or a patent under reexamination. A judicially created double patenting rejection may be obviated by filing a terminal disclaimer in accordance with § 1.321(c).

[Added, 61 FR 42790, Aug. 19, 1996, effective Sept. 23, 1996; heading and para. (a) revised, 65 FR 57024, Sept. 20, 2000, effective Nov. 29, 2000]

### § 1.131 Affidavit or declaration of prior invention.

(a) When any claim of an application or a patent under reexamination is rejected, the inventor of the subject matter of the rejected claim, the owner of the patent under reexamination, or the party qualified under §§ 1.42, 1.43, or 1.47, may submit an appropriate oath or declaration to establish invention of the subject matter of the rejected claim prior to the effective date of the reference or activity on which the rejection is based. The effective date of a U.S. patent, U.S. patent application publication, or international application publication under PCT Article 21(2) is the earlier of its publication date or date that it is effective as a reference under 35 U.S.C. 102(e). Prior invention may not be established under this section in any country other than the United States, a NAFTA country, or

a WTO member country. Prior invention may not be established under this section before December 8, 1993, in a NAFTA country other than the United States, or before January 1, 1996, in a WTO member country other than a NAFTA country. Prior invention may not be established under this section if either:

(1) The rejection is based upon a U.S. patent or U.S. patent application publication of a pending or patented application to another or others which claims the same patentable invention as defined in § 1.601(n); or

(2) The rejection is based upon a statutory bar.

(b) The showing of facts shall be such, in character and weight, as to establish reduction to practice prior to the effective date of the reference, or conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application. Original exhibits of drawings or records, or photocopies thereof, must accompany and form part of the affidavit or declaration or their absence satisfactorily explained.

[24 FR 10332, Dec. 22, 1959; 34 FR 18857, Nov. 26, 1969; para. (a), 48 FR 2713, Jan. 20, 1983, effective Feb. 27, 1983; para. (a), 50 FR 9381, Mar. 7, 1985, effective May 8, 1985; 50 FR 11366, Mar. 21, 1985; 53 FR 23733, June 23, 1988, effective Sept. 12, 1988; para. (a)(1) revised and para. (a)(2) added, 60 FR 21043, May 1, 1995, effective May 31, 1995; para. (a) revised, 61 FR 42790, Aug. 19, 1996, effective Sept. 23, 1996; heading and para. (a) revised, 65 FR 54604, Sept. 8, 2000, effective Sept. 8, 2000; para. (a) revised, 65 FR 57024, Sept. 20, 2000, effective Nov. 29, 2000]

### § 1.132 Affidavits or declarations traversing rejections or objections.

When any claim of an application or a patent under reexamination is rejected or objected to, any evidence submitted to traverse the rejection or objection on a basis not otherwise provided for must be by way of an oath or declaration under this section.

[48 FR 2713, Jan. 20, 1983, effective Feb. 27, 1983; revised, 61 FR 42790, Aug. 19, 1996, effective Sept. 23, 1996; revised, 65 FR 54604, Sept. 8, 2000, effective Sept. 8, 2000; revised 65 FR 57024, Sept. 20, 2000, effective Nov. 29, 2000]